ANDA 75-881 March 29, 2001

Gensia Sicor Pharmaceuticals, Inc.
Attention: Elvia O. Gustavson
19 Hughes
Irvine, CA 92618-1902

Dear Madam:

This is in reference to your abbreviated new drug application dated May 19, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Levocarnitine Injection USP, 200 mg/mL (packaged in 500 mg/2.5 mL, 1 g/5 mL, and 2.5 g/12.5 mL single-dose vials).

Reference is also made to your amendments dated January 19 and February 14, 2001.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Levocarnitine Injection USP, 200 mg/mL, 500 mg/2.5 mL and 1 g/5 mL vials to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Carnitor® Injection, 200 mg/mL, 500 mg/2.5 mL and 1 g/5 mL vials, respectively, of Sigma Tau Pharmaceuticals, Inc.) In addition, your Levocarnitine Injection USP, 200 mg/mL, 2.5 g/12.5 mL vial, can be expected to provide the same therapeutic effect as that of equivalent doses of Carnitor Injection upon which the Agency relied as the basis of safety and effectiveness. We note that Gensia Sicor Pharmaceuticals, Inc. obtained authorization to include the 2.5 g/12.5 mL strength in this application through a petition submitted under Section 505(j)(2)(C) of the Act and approved on September 16, 1999.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research